

Signature



NOV 0 5 2003

RECEIVED

# **TECH CENTER 1600/2900**

Date

Oct. 31, 2003

### **Application Number** 10/002,631 **TRANSMITTAL Filing Date** October 31, 2001 **FORM** Graff **First Named Inventor** (to be used for all correspondence after initial filing) Group Art Unit 1636 Lambertson, M **Examiner Name** A34943 090495.0243 Attorney Docket Number Total Number of Pages in This Submission **ENCLOSURES** (check all that apply) After Allowance Communication Assignment Papers Fee Transmittal Form (for an Application) Appeal Communication to Board Fee Attached Drawing(s) of Appeals and Interferences Licensing-related Papers Appeal Communication to Group Amendment / Reply (Appeal Notice, Brief, Reply Brief) Petition After Final **Proprietary Information** Petition to Convert to a Affidavits/declaration(s) **Provisional Application** Status Letter Power of Attorney, Revocation Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request identify below): Terminal Disclaimer Express Abandonment Request Request for Refund Information Disclosure Statement CD, Number of CD(s) Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT BakerBotts LLP Firm 30 Rockefeller Plaza Individual name NY 10112 Att Name: Rochelle K. Seide Signature PTO Reg: 32,300 Date Oct. 31, 2003 **CERTIFICATE OF MAILING** I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box11450, Alexandria, VA 22313-1450 on this date: Oct. 31, 2003 Typed or printed name Rochelle K. Seide

## **RECEIVED**

NOV 0 5 2003

# BAKER BOTTS

NOV 0 3 2003 8

FEE TRANSMITT for FY 2003

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

Signature

	TECH CENTER 1800/2900
Ce	omplete if Known
Application Number	10/002,631
Filing Date	October 31, 2001
First Named Inventor	Graff
Examiner Name	Lambertson, M
Art Unit	1636
Attorney Docket No.	A34943 090495.0243

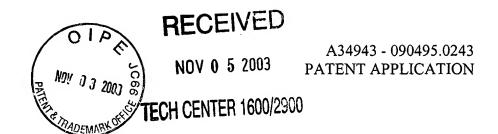
Date

Oct. 31, 2003

TOTAL AMOUNT OF PAYMENT (\$) U		Attor	ney Do	cket N	No. A34943 090495.0243
METHOD OF PAYMENT (check all that apply)				FEI	E CALCULATION (continued)
Check Credit card Money Other None	3. Al	DDITI	ONA	L FEE	S
Order Order	Large I	Entity	Smal	Entity	1
Deposit Account 02-4377	Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description Fee Paid
Number	1051	130	2051	65	Surcharge - late filing fee or oath
Deposit Account Name Baker Botts LLP	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet
The Commissioner is authorized to: (check all that apply)	1053	130	1053	130	Non-English specification
Charge fee(s) indicated below Credit any overpayments	1812	2,520	1812	2,520	For filing a request for ex parte reexamination
Charge any additional fee required under 37CFR 1.16 and 1.17	1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action
	1251	110	2251	55	Extension for reply within first month
FEE CALCULATION	1252	420	2252	210	Extension for reply within second month
1. BASIC FILING FEE Large Entity Small Entity	1253	950	2253		
Fee Fee Fee Fee Fee Description Fee Paid Code (\$)	1254	1,480	2254	740	Extension for reply within fourth month
1001 770 2001 385 Utility filing fee	1255	2,010	2255	1,005	Extension for reply within fifth month
1002 340 2002 170 Design filing fee	1401	330	2401	165	Notice of Appeal
1003 530 2003 265 Plant filing fee	1402	330	2402	165	
1004 770 2004 385 Reissue filing fee	1403	290	2403	145	Request for oral hearing
1005 160 2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to institute a public use proceeding
SUBTOTAL (1) (\$) 0	1452	110	2452	55	Petition to revive - unavoidable
	1453	1,300	2453	650	Petition to revive - unintentional
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1501 ·	1,330	2501	665	Utility issue fee (or reissue)
Extra Claims below Fee Paid  Total Claims 20 = 0 x = 0	1502	480	2502	240	Design issue fee
Independent 20 0 0	1503	630	2503	315	Plant issue fee
Claims - 3 = 0 X = 0 Multiple Dependent	1460	130	1460	130	Petitions to the Commissioner
	1807	50	1807	50	Processing fee under 37 CFR 1.17(q)
Large Entity   Small Entity Fee Fee Fee Fee Description	1806	180	1806		Submission of Information Disclosure Stmt
Code (\$) Code (\$)	8021	40	8021	40	Recording each patent assignment per property (times number of properties)
1202 18 2202 9 Claims in excess of 20 1201 86 2201 43 Independent claims in excess of 3	1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))
1203 290 2203 145 Multiple dependent claim, if not paid	1810	770	2810	385	For each additional invention to be
1204 86 2204 43 ** Reissue independent claims over original patent	1801	770	2801	385	examined (37 CFR 1.129(b))  Request for Continued Examination (RCE)
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent	1802	900	1802	900	Request for expedited examination
_	Other fo	ee (sne	cify)		of a design application
SUBTOTAL (2) (\$)0				iling Fe	ee Paid SUBTOTAL (3) (\$)0
**or number previously paid, if greate; For Reissues, see above					305101AE (3)  (\$)0
SUBMITTED BY	D.	aistrot	ion Me	_	(Complete (if applicable)
Name (Print/Type)   Rookalla K Saida // [/	Re	egistrat	un NO.	122	200 Telephone 242 400 0500

BAKER BOTTS LLP Attorney Docket Number: A34943 090495.0243

itle:	METHOD TO	IDENTIFY SIGNAL	SEQUENCES			
Use Spa	e Below for Addi	itional Information	٠.			
Osc Spac	c Delow for Addi					
	determinen stadigarisaj (1970) (1970) til bilder kirje og og okunstadijanjen og oggjenne er oggjenner og oggjenner					
					;	
				·	:	
					÷	
			·		;	
					;	
					:	
					•	



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

Graff et al.

Serial No.

10/002,631

Examiner

Lambertson, D

Filed

October 31, 2001

Group Art Unit:

1645

For

METHOD TO IDENTIFY SIGNAL SEQUENCES

## RESPONSE TO RESTRICTION REQUIREMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

October 31, 2003

Date of Deposit

Rochelle K. Seide Attorney Name 32,300

Registration No.

<u>yuu</u>

October 31, 2003

Date of Signature

Commissioner for Patents Box 1450

Alexandria, VA 22313-1450

Sir:

This is paper is submitted in response to the Office Communication dated October 2, 2003 in the above-identified application in which the Examiner issued a restriction requirement. The Examiner has required the selection of one of three groups of claims for prosecution in this application:

Group I: claims 114-128 and 135-144, drawn to a method for identifying a candidate nucleic acid encoding a signal/transmembrane sequence;

Group II: claims 129, drawn to a method of identifying the function of a polypeptide having a signal/transmembrane sequence; and

Group III: claims 130-134, drawn to a method of correlating the function of a nucleic acid or polypeptide having a signal/transmembrane sequence to a disease state or other physiological condition.

The Examiner asserts that the inventions of Group I and II are unrelated. Specifically, the Examiner alleges that the outcome of the claims of Group I is the identification of a nucleic acid sequence that encodes an amino acid with the capacity to traverse biological membranes, and involves method steps where it is determined if such a sequence is encoded by the nucleic acid that is being tested. The Examiner alleges that the invention of Group II requires different method steps, wherein the function of a polypeptide having a signal sequence is determined. The Examiner further alleges that the function of each polypeptide has a different function and could be variegated. The Examiner alleges that these functions are clearly different from determining whether a polypeptide has the ability to traverse a biological membrane. Because these inventions allegedly have different functions and modes of operation, the Examiner asserts that they are patentably distinct.

The Examiner asserts that the inventions of Group I and III are unrelated. The Examiner further alleges that the invention of Group III also requires different method steps from the invention of Group I and has a different function of a polypeptide having a signal sequence correlated to a disease condition. The Examiner further alleges that the determination of whether a particular protein is associated with a disease state results in an outcome that is different from the identification of a transmembrane sequence. The Examiner alleges that the invention of Group III requires different method steps such as the determination of a disease

NY02:463908.1

state, for example the showing that there is a corresponding mutation on a gene encoding a protein with a transmembrane sequence. Because these inventions allegedly have different functions and modes of operation, the Examiner asserts that the inventions are patentably distinct.

The Examiner also asserts that the inventions of Group II and III are unrelated. The Examiner alleges that the invention of Group II involves a determination of function for a polypeptide, requiring biochemical examination to associate the polypeptide with a particular activity. The Examiner alleges that the invention of Group III requires that one determine that a disease state is related to a mutation in a protein having a signal sequence. The Examiner alleges that the inventions utilize different method steps to arrive at different outcomes, e.g. the identification of a biochemical activity activity versus the correlation of disease state with a mutated transmembrane sequence containing protein. Because these inventions allegedly have different functions and modes of operation, the Examiner asserts that the inventions are patentably distinct.

Furthermore, the Examiner alleges that the inventions have separate status in the art due to their different classification. The Examiner further allege that in instances where the classification are the same, the non-patent literature searches are not co-extensive, causing the searches to be burdensome.

Applicant respectfully traverses. There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP § 802.01, § 806.04 and § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) There must be a serious burden on the Examiner if restriction is required (see MPEP § 808.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). The term "independent"

NY02:463908.1

(i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect. (Emphasis supplied, MPEP § 802.01). Moreover, MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it contains claims to distinct or independent inventions." (Emphasis supplied).

Applicant submits that the inventions of Group I, II and III are not independent. The inventions of Group II and III are clearly connected to the invention of Group I. The steps comprising the method recited in the claims of Group I lead to the identification of a eukaryotic nucleic acid encoding a secreted protein. Applicants submit that the identification of the "candidate eukaryotic nucleic acid that encodes a polypeptide," as recited in claims 114, encompasses, not only a mere identification of the sequence of the polypeptide, but also includes an analysis of the function of the polypeptide. The requirement that the polypeptide be a secreted protein is one criteria used for the identification of the nucleic acid and its corresponding polypeptide comprising a signal sequence. The use of the secretory property in the identification of the candidate polypeptide does not preclude one from an additional related step of analyzing the function of the polypeptide. Accordingly, the analysis of whether the identified candidate polypeptide can be correlated to a disease condition is also encompassed by goal-of-identifying-a-candidate-eukaryotic-nucleic-acid-that-encodes-a-polypeptide-having-asignal/transmembrane sequence. All the inventions of Groups I, II and III share the common goal of identification of a candidate eukaryotic nucleic acid that encodes a polypeptide. Thus, applicant submits that the additional steps recited in inventions of Group II and III are clearly related to Group I and to each other.

In conclusion, Applicant asserts that the claims of Groups I-III are connected by a disclosed relationship and, therefore, should be examined together. Applicant further submits that the claims are connected by a single, searchable unifying relationship, and that the Examiner would not, therefore, be seriously burdened by searching and examining the claims of these groups in a single application. Accordingly, Applicant requests withdrawal of the restriction requirement.

However, should the Examiner remain unpersuaded by Applicant's arguments regarding the relationship of the claims, Applicant elects Group I, with traverse, consisting of Claims 114-128 and 135-144, drawn to a method for identifying a candidate nucleic acid encoding a signal/transmembrane sequence.

## **CONCLUSION**

On the basis of the foregoing remarks, Applicant requests reconsideration and withdrawal of the rejection under 35 U.S.C. §121. Applicant respectfully submits that the claims on file are ready for examination and in condition for allowance.

Respectfully submitted,

Rochelle K. Seide

Patent Registration No. 32,300

Attorney for Applicants

BAKER BOTTS L.L.P. 30 Rockefeller Plaza, 44th Floor New York, New York 10112 (212) 408-2500